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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 25

Application Number: 09/165,460
Filing Date: October 02, 1998
Appellant(s): RINE ET AL.

Richard Aron Osman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/14/2002.

(1) Real Party in Interest

A statement identifying the real party in interest

(2) Related Appeals and Interferences

The brief contains a statement indicating that Appellants are unaware

appeals or interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is substantially correct. It is noted however that it is the polynucleotide of SEQ ID NO: 3 which encodes the product of the gene RCE1 and not the polynucleotide of SEQ ID NO: 2 as asserted in page 2 of the Brief.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. In regard to claims 33-34 and 41-42, it is noted however that the polynucleotide of SEQ ID NO: 1 is identical to the polynucleotide of Rose et al. except for one mismatch at position 1664. See attached alignment provided for visualization purposes. The protein encoded by the polynucleotide of Rose et al. (Swiss Prot accession number P47154, February 1, 1996) is identical to the polypeptide of SEQ ID NO: 2 except for one mismatch at position 441. See attached alignment provided for visualization purposes. Since Rose et al. does not teach a

polynucleotide which encodes the polypeptide of SEQ ID NO: 2 in its entirety, the teachings of Rose et al. do not anticipate or make obvious the expression vector and host cells of claims 33-34 and 41-42, therefore the 35 USC 103(a) rejection is hereby withdrawn as it applies to claims 33-34 and 41-42.

(7) Grouping of Claims

The brief contains a statement indicating that the claims in each of the issues shall stand together as a group.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Rose et al., GenBank accession number Z49617, October 6, 1995.

Lye et al., GenBank accession number Z49260, May 16, 1995.

4,997,767	NOZAKI	3-1991

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 31 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. (GenBank accession number Z49617, October 6, 1995) in view of Nozaki et al. (U.S. Patent No. 4,997,767, March 1991). Rose et al. teaches a polynucleotide of 1825 nucleotides (locus

SCYJR117W) which is identical to that of the polynucleotide of SEQ ID NO: 1 (1825 nucleotides) except for one mismatch at position 1664. See attached alignment provided for visualization purposes. The polynucleotide of Rose et al. would be expected to hybridize to the polynucleotide of SEQ ID NO: 1 under highly stringent conditions. Rose et al. does not teach an expression vector comprising said polynucleotide or a host cell transformed with an expression vector. Nozaki et al. teaches a yeast shuttle vector which comprises the repressible acid phosphatase promoter (column 1, lines 4-10) for expressing proteins in yeast which can replicate in E. coli and yeast. Nozaki et al. also teaches the transformation of yeast cells with such vector (column 7, line 50- column 8, line 27). Nozaki et al. does not teach a vector or a host cell comprising a polynucleotide which can hybridize under highly stringent conditions to the polynucleotide of SEQ ID NO: 1.

Claim 31 is directed to an expression vector comprising a polynucleotide operably linked to a promoter, wherein said polynucleotide hybridizes under highly stringent conditions to the polynucleotide of SEQ ID NO: 1 and wherein said polynucleotide encodes a polypeptide which mediates the proteolytic removal of an AAX tripeptide from a prenylated CAAX protein. Claim 39 is directed to a cell transformed with the vector of claim 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an expression vector, as taught by Nozaki et al., with the polynucleotide of Rose et al. and transform a host cell for the benefit of recombinantly producing sufficient amounts of the corresponding protein for functional characterization and determination of its biological role. A person of ordinary skill in the art is highly motivated to characterize and determine the biological role of a yeast (S. cerevisiae) protein since yeast is a unicellular

eukaryote widely studied in the art for identification of proteins and/or biological processes which may be found in higher eukaryotes including humans. One of ordinary skill in the art has a reasonable expectation of success at making an expression vector with the polynucleotide of Rose et al. and transforming a host cell with such vector since Nozaki et al. teaches an expression vector which can be used in E. coli and yeast as well as the transformation of host cells with such vector. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Claims 35, 37-38, 43, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lye et al. (GenBank accession number Z49260, May 16, 1995) in view of Nozaki et al. (U.S. Patent No. 4,997,767, March 1991). Lye et al. teaches a polynucleotide of (locus SC8156) which comprises the polynucleotide of SEQ ID NO: 3 in its entirety. See attached alignment provided for visualization purposes. The polynucleotide of Lye et al. would be expected to hybridize to the polynucleotide of SEQ ID NO: 3 under highly stringent conditions. Lye et al. does not teach an expression vector comprising said polynucleotide or a host cell transformed with an expression vector. Nozaki et al. teaches a yeast shuttle vector which comprises the repressible acid phosphatase promoter (column 1, lines 4-10) for expressing proteins in yeast which can replicate in E. coli and yeast. Nozaki et al. also teaches the transformation of yeast cells with such vector (column 7, line 50- column 8, line 27). Nozaki et al. does not teach a vector or a host cell comprising a polynucleotide which can hybridize under highly stringent conditions to the polynucleotide of SEQ ID NO: 3.

Claim 35 is directed to an expression vector comprising a polynucleotide operably linked to a promoter, wherein said polynucleotide hybridizes under highly stringent conditions to the polynucleotide of SEQ ID NO: 3 and wherein said polynucleotide encodes a polypeptide which mediates the proteolytic removal of an AAX tripeptide from a prenylated CAAX protein. Claims 37 and 38 are directed to the expression vector of claim 35 wherein the polypeptide either comprises or consists of the polypeptide of SEQ ID NO: 4. Claims 43, 45 and 46 are drawn to host cells transformed with the vectors of claims 35, 37 and 38, respectively.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an expression vector, as taught by Nozaki et al., with the polynucleotide of Lye et al. and transform a host cell for the benefit of recombinantly producing sufficient amounts of the corresponding protein for functional characterization and determination of its biological role. A person of ordinary skill in the art is highly motivated to characterize and determine the biological role of a yeast (S. cerevisiae) protein since yeast is a unicellular eukaryote widely studied in the art for identification of proteins and/or biological processes which may be found in higher eukaryotes including humans. One of ordinary skill in the art has a reasonable expectation of success at making an expression vector with the polynucleotide of Lye et al. and transforming a host cell with such vector since Nozaki et al. teaches an expression vector which can be used in E. coli and yeast as well as the transformation of host cells with such vector. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

(11) Response to Argument

Issue I: Claims 31 and 39 are patentable under 35 USC 103(a)

It is noted that the 35 USC 103(a) rejection as it applies to claims 33-34 and 41-42 has been withdrawn for the reasons set forth under Issues. Any specific arguments in regard to claims 33-34 and 41-42 are now moot in view of the withdrawal of the instant rejection as it applies to these claims.

In page 3, first paragraph of the argument, Appellants argue that the Examiner's rejection of claims 31 and 39 over Rose et al. in view of Nozaki et al. is not in compliance with the notice requirement of 35 USC 132, which requires reason and information and references useful in judging the propriety of the rejection.

It is unclear to the Examiner as to which is the information or references which were not submitted to Appellants to judge the propriety of the rejection. As indicated in previous Office Action Paper No. 20, paragraph 2, mailed on 2/2/1/2002, PTO records indicate that the references cited by the prior Examiner of record were submitted to Appellants. In case these references were misplaced previously, the present Examiner submitted a duplicate of these references with Paper No. 20. Since Appellants do not clearly indicate which is the information/references which are missing, the present Examiner cannot determine from Appellant's argument, which is the information that Appellants were not provided with by the previous Examiner of record.

In page 3, second paragraph of the argument, Appellants argue that the entry by Rose et al. (GenBank accession number Z49617) is dated August 11, 1997, which is more than a year

after the priority date claimed by Appellants, August 7, 1996, therefore it is not prior art. Appellants submit that the Examiner has hand-written on the NCBI printout "Public Availability: 10/6/1995". Appellants further argue that upon a telephone inquiry, the Examiner indicated that the support for his hand-written comment was a "creation date" annotation associated with the GenBank entry however Appellants assert that the annotation indicates that the entry was updated on August 11, 1997.

It is noted for the record that the present Examiner did not submit Appellants a hand-written publication date on an NCBI printout as alleged. Furthermore, the present Examiner did not have a telephonic conversation with Appellants to discuss the hand-written annotation as alleged. In regard to arguments that entry Z49617 was first available to the public on August 11, 1997, it is noted that the creation date of the entry is the date when it is first available to the public, which in this case is October 6, 1995. The PTO Biotechnology and Chemical Library has contacted EMBL to determine the date of public availability of entry Z49617 and a copy of an e-mail communication with a representative of EMBL is submitted herein. Z49617 was first submitted to the EMBL databank. As it can be seen in such e-mail, it is clearly stated that the date given in the first DT line of the entry is the date the entry first became available for public disclosure. Therefore, for entry Z49617, that date corresponds to October 6, 1995, as shown in the attached e-mail. In the absence of any evidence which would suggest that the sequence in the instant entry was modified in 1997 or that there was a request to withhold its public disclosure until 1997, the Examiner must assume that the instant entry was first disclosed to the public on October 6, 1995.

In page 3, last paragraph, and continuing in page 4, Appellants argue that the creation date of an EMBL or GenBank record is not the public availability date. Appellants argue that in many cases, these records are maintained in secrecy until a predetermined publication or patent filing date is effected. Furthermore, Appellants argue that the creation date often doe not reflect the record as subsequently published and that electronic databases such as GenBank or EMBL are constantly updating, amending, annotating or supplementing their records. According to Appellants, the newer editions retain the creation date of the original record but were not in existence at the creation date. It is Appellant's position that the Examiner seeks to rely on a creation date for a record which could not have logically existed on that creation date. Appellants further argue that they have provided copies of GenBank and EMBL information in regard to submissions as evidence of withholding public availability of records after submission and record creation as well as a sample of a GenBank record as evidence of the lack of agreement between the date of the last modification and the release date.

The Examiner acknowledges (1) submissions may be withheld for public disclosure until a predetermined publication or patent filing date is effected, (2) entries in EMBL or GenBank are constantly being updated, amended or annotated, and (3) Appellant's submission of information for submitters of data to GenBank and EMBL as well as the submission of a sample GenBank record, however these arguments have not been found persuasive to overcome the rejection for the following reasons. As indicated by Appellants and known in the art, when submissions to data banks such as GenBank or EMBL are made, authors can request to withhold public disclosure until an author-specified date. The date when the submission is made to GenBank or EMBL is called "submission date" and it should never be used for prior art purposes

in view of the fact that public disclosure of the entry may have been delayed for the reasons set forth above. The date when the entry is first released to the public is called "creation date", as evidenced by the e-mail communication submitted herein. In the instant case, entry Z49617 has a submission date of September 25, 1995 as indicated in the GenBank entry under "Journal", which is not the date used by the Examiner for prior art purposes but rather the creation date, which is October 6, 1995.

Appellants have presented no evidence which would suggest that the polynucleotide disclosed by Rose et al. was withheld from public disclosure after its creation date or that it was updated or amended to the extent that its sequence is different from what it was when it was created in October 6, 1995. The Examiner acknowledges that entry Z49617 was updated in August 11, 1997. However there is no evidence in the record as disclosed in GenBank or provided by Appellants which suggest that this update resulted in a different sequence from what was available in October 6, 1995. As indicated by Appellants, GenBank and EMBL are constantly updating, annotating and/or supplementing their records. Therefore, the update of August 11, 1997 could have been a new annotation, a typographical correction, an additional author added, etc. The National Center for Biotechnology Information (NCBI) website http://www.ncbi.nlm.nih.gov:80/entrez/sutils/girevhist.cgi, provides a Sequence Revision History tool which allows one to access the different versions, GI numbers and update dates for sequences. The existence of this tool is also disclosed in the sample GenBank record provided by Appellants in page 8, under "Version". As known in the art and also disclosed in the sample GenBank record provided by Appellants (pages 8-9, "Version" and "GI"), if there are changes made to a sequence, the version number will increase and the GI (GenInfo Identifier) number

will also change. A copy of (1) the sequence corresponding to entry Z49617 as of its creation date, October 6, 1995, the sequence corresponding to entry Z49617 as of August 11, 1997, and a copy of the sequence revision history for entry Z49617 are submitted herein. Z49617 was first seen at NCBI on October 8, 1995. As shown in the revision history, there are no changes to the GI or version numbers for this entry which would indicate changes in sequence. Furthermore, a comparison of the sequences as of October 6, 1995 and August 11, 1997 do not appear to show any changes in sequence. Therefore, in the absence of any evidence which would suggest that the sequence in the instant entry was modified in 1997 or that there was a request to withhold its public disclosure until 1997, the Examiner must assume that the instant entry was first disclosed to the public on October 6, 1995.

In page 4, second paragraph, Appellants submit that the Examiner seeks to shift the burden to Appellants to prove that Rose et al. is not prior art. Appellants argue that this imposes an inherently impossible proof on Appellants. It is Appellant's position that the Examiner should allow the pending claims unless a prima facie case of unpatentability can be established. Appellants submit that the evidence unequivocally demonstrates that Rose et al. was not publicly available as of October 6, 1995.

The Examiner disagrees with Appellant's contention that the Examiner has not established a prima facie case of unpatentability. As indicated above, a representative from EMBL has indicated that the creation data is the date when an entry is first disclosed to the public. In addition, while it is agreed that the entry was modified on August 11, 1997, there is no evidence in the record or provided by Appellants that the modification resulted in a sequence change. As indicated above, the sequence revision history provided herein clearly indicates that

no changes have been made based on the fact that the GI and version numbers are the same throughout the history of the entry. Furthermore, there is no evidence that entry Z49617 was withheld from public disclosure until 1997. Therefore, in view of the information provided by EMBL, as evidenced by the e-mail communication provided, and the information disclosed by NCBI as discussed above, one would reasonably conclude that the creation date of entry Z49617 is the date of public availability and that no sequence changes have been made to such entry. As such, the polynucleotide of Rose et al. is considered valid prior art.

In page 4, last paragraph, and the beginning of page 5, Appellants submit that the entire yeast genome had been largely sequenced prior to the filing of their patent application, including the identification of thousands of potential open reading frames (ORF), i.e. polynucleotides which can encode proteins. However, Appellants argue that the sequence of the yeast genome is just an inherent property of the prior art genome itself and provides no more suggestion for isolating, recombinantly expressing and using a particular gene than does the unsequenced yeast genome. Furthermore, Appellants argue that a computer-predicted ORF may not necessarily encode a functional mRNA and even if these ORFs have a sequence similar to that required in their expression vectors, the claimed vectors would not be anticipated or obvious. Appellants argue that the claimed vectors are not obvious since they do not encompass any natural yeast chromosome and require that the recited coding sequence be operably linked to a promoter. It is Appellant's contention that in the absence of any evidence for function, there would be no motivation to select one of thousands of potential yeast ORFs of unknown function and operably link it to a promoter in an expression vector.

While one could argue that computer predicted ORF may not necessarily encode a functional mRNA, the Examiner disagrees with Appellant's contention that if an ORF is known, there is no motivation to make an expression vector comprising said ORF if the function is unknown. On the contrary, once an ORF is known, one would be highly motivated to construct an expression vector with the ORF linked to a promoter, transform a host cell and recombinantly produce the corresponding protein in order to characterize the protein and determine its biological function. It is noted that a promoter is essential for expression in a host cell, therefore one would have to use a promoter for expression and production of the corresponding protein. In this particular case, as indicated above, one is motivated to characterize and determine the biological role of a yeast protein since yeast is a unicellular eukaryote widely studied in the art for identification of proteins and/or biological processes which may be found in higher eukaryotes including humans. Therefore, for the reasons set forth above, the construction of the claimed vector and transformation of the claimed host cell would have been obvious at the time the invention was made.

Issue II: Claims 35, 37-38, 43 and 4-46 are patentable under 35 USC 103(a)

In page 5, first paragraph, Appellants argue that the Examiner's rejection of claims 35, 37-38, 43 and 45-46 over Lye et al. in view of Nozaki et al. is not in compliance with the notice requirement of 35 USC 132, which requires reason and information and references useful in judging the propriety of the rejection.

It is unclear to the Examiner as to which is the information or references which were not submitted to Appellants to judge the propriety of the rejection. As indicated in previous Office Action Paper No. 20, paragraph 2, mailed on 2/2/1/2002, PTO records indicate that the references cited by the prior Examiner of record were submitted to Appellants. In case these references were previously misplaced, the present Examiner submitted a duplicate of these references with Paper No. 20. Since Appellants do not clearly indicate which is the information/references which are missing, the present Examiner cannot determine from Appellant's argument, which is the information that Appellants were not provided with by the previous Examiner of record.

In page 5, second paragraph, Appellants argue that Lye et al. is not prior art since it is dated August 11, 1997, more than a year after the priority date claimed by Appellants, which is August 7, 1996. Appellants argue that the Examiner is relying on a purported unpublished submission date which is improper and that no evidence has been presented that the sequence in entry Z49260 was published before August 11, 1997.

In regard to Appellant's contention that Lye et al. is not proper prior art, it is noted that according to EMBL records, the date entry Z49260 (Locus SC8156) was first available to the public is May 16, 1995, which is not the date when the entry was first submitted but rather when it was created, i.e. publicly available. The submission date is May 12, 1995. The PTO Biotechnology and Chemical Library has contacted EMBL to determine the date of public availability of entry Z49260 and a copy of an e-mail communication with a representative of EMBL is submitted herein. Z49260 was first submitted to the EMBL databank. As it can be seen in such e-mail, it is clearly stated that the date given in the first DT line of the entry is the

date the entry first became available for public disclosure. Therefore, for entry Z49260, that date corresponds to May 16, 1995, as shown in the attached e-mail.

The Examiner acknowledges that entry Z49260 was updated in August 11, 1997. However there is no evidence in the record as disclosed in GenBank/EMBL or provided by Appellants which suggest that this update resulted in a different sequence from what was available in May 16, 1995. As indicated by Appellants, GenBank and EMBL are constantly updating, annotating and/or supplementing their records, therefore the update of August 11, 1997 could have been a new annotation, a typographical correction, an additional author added, etc. As indicated above, the National Center for Biotechnology Information (NCBI) website http://www.ncbi.nlm.nih.gov:80/entrez/sutils/girevhist.cgi, provides a Sequence Revision History tool which allows one to access the different versions, GI numbers and update dates for sequences. The existence of this tool is also disclosed in the sample GenBank record provided by Appellants in page 8, under "Version". A copy of (1) the sequence corresponding to entry Z49260 as of its creation date, May 16, 1995, the sequence corresponding to entry Z49260 as of August 11, 1997, and a copy of the sequence revision history for entry Z49260 are submitted herein. Z49260 was first seen at NCBI on May 19, 1995. As shown in the revision history, there are no changes to the GI or version numbers for this entry which would indicate changes in sequence. Appellants have presented no evidence which would suggest that the polynucleotide disclosed by Lye et al. was withheld from public disclosure after its creation date or that it was updated or amended to the extent that its sequence is different from what it was when it was created in May 16, 1995. In the absence of any evidence which would suggest that the sequence in the instant entry was modified in 1997 or that there was a request to withhold its public

disclosure until 1997, the Examiner must assume that the instant entry was first disclosed to the public on May 16, 1995. Therefore, in view of the information provided by EMBL, as evidenced by the e-mail communication provided, and the information disclosed by NCBI, one would reasonably conclude that the creation date of entry Z49260 is the date of public availability and that no sequence changes have been made to such entry. As such, the polynucleotide of Lye et al. is considered valid prior art.

In page 5, third paragraph, continuing in page 6, Appellants submit that as previously discussed, the entire yeast genome had been sequenced prior to the filing of the instant application, including the identification of potential ORFs which may not even encode a functional mRNA. Appellants argue that Lye et al. discloses computer prediction of thousands of possible CDS regions. Appellants submit that the predictions of Lye et al. are the result of a computer programmed to input raw genomic sequences, select all possible CDS regions over 100 codons, and then exclude those that are more than 50% overlapped by a larger predicted CDS. Appellants assert that Lye et al. indicates that CDS regions of the initial dataset are available upon request and that the reference teaches algorithm-predicted PROSITE database matches which according to Lye et al. may be fortuitous. According to Appellants, Lye et al. does not disclose any gene or gene product but the results of a first run effort to sequence the entire XIII chromosome of S. cerevisiae and that the information provided by Lye et al is just a sequence which is an inherent property of the chromosome. Appellants submit that the Examiner uses Appellant's disclosure to find a motivation to create an expression vector. It is Appellant's contention that in the absence of any evidence of function, there is no motivation to select one out of thousands of ORFs of unknown function and operably link it to a promoter in an

expression vector. It is Appellant's opinion that since there is no prior art suggestion of the function of the polynucleotide of SEQ ID NO: 1 or 3, cloning and expression of such polynucleotide using the techniques taught by Nozaki et al. or Sambrook et al., is not obvious and the claims are in compliance with 35 USC 102 and 103.

The Examiner acknowledges that (1) a predicted ORF may not encode a functional mRNA, (2) the method used by Lye et al. in regard to predictions of ORFs, and (3) the PROSITE database matches may be fortuitous. However the Examiner disagrees with Appellant's contention that there is no motivation to construct a vector in the absence of prior art suggestion of function. While Appellants may have empirically determined the function of the polynucleotide of SEQ ID NO: 3 and that of the corresponding protein (SEQ ID NO: 4), at the time the invention was made, it was known that the polynucleotide of SEQ ID NO: 3 was a potential open reading frame (ORF), i.e. polynucleotide encoding a protein. As such, as indicated above, one would be highly motivated to construct a vector comprising the polynucleotide of Lye et al. linked to a promoter to allow expression of the corresponding protein in a host cell, and transform a host cell with such vector for characterization of the protein and determination of its biological function. Also, as indicated above, one would link the polynucleotide (ORF) to a promoter since this is essential for expression in the host cell. One is motivated to characterize and determine the biological function of the yeast protein since yeast is a unicellular eukaryote widely studied in the art for identification of proteins and/or biological processes which may be found in higher eukaryotes including humans. In regard to arguments that the Examiner uses Appellant's disclosure to find a motivation to create an expression vector, it is noted that the motivation given by the prior Examiner of record or the present Examiner is

not the same motivation disclosed by Appellants. Therefore, for the reasons set forth above, the construction of the claimed vector and transformation of the claimed host cell with such vector would have been obvious at the time the invention was made.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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DR
May 16, 2003

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